

REMARKS

The Applicants have carefully considered the Office Action dated April 3, 2009. In response, the Applicants present the foregoing amended claims. Based on the amendments and the remarks that follow, reconsideration of the patentability of the claims is respectfully requested.

Initially, the Examiner rejects claims 14-19 and 21 under 35 U.S.C. §112, 2d paragraph. In response, claim 14 is amended to delete the term "suitable." The skilled artisan in this field, that is, animal feeds, feed supplements, and feeding practices, readily recognizes the scope of the term "feed grade carrier" as used in the context of a disclosure relating to animal feeds, feed supplements, and the like. The Examiner is again referred to **Exhibit A** appended to the response filed by the Applicant on 21 January, 2009 (that paper is incorporated into the present response by reference). As shown in the 1999 Official Publication of the Association of American Feed Control Officials, Inc. (AAFCO), on page 171, AAFCO recognizes the term "carrier" as referring to "[A]n edible material to which ingredients are added to facilitate uniform incorporation of the latter into feeds." It is believed that amended claim 14 and its progeny are perfectly definite, and reconsideration of the Section 112 rejection is respectfully requested.

Next, the Examiner rejects claims 1-3, 5-10, 12-19, and 21 under 35 U.S.C. §102(b) over U.S. Published Patent Appl. No. 2002/0037342 (the Labeille reference). Respectfully, the Applicant reiterates that Labeille neither teaches nor provides an articulated reason for the skilled artisan to consider the subject matter of the present independent claims as amended, that is, the precise alterations in protein, fat, and dry matter content of the recited fibrous by-product or residue of the present invention as claimed. Nowhere does Labeille expressly teach these proportions, certainly

not in an enabling manner. Even more, the skilled artisan is provided no articulated reason for considering these proportions by any teaching of Labeille, since Labeille focuses exclusively on the enzyme content of its end product, rather than giving any consideration to improving nutritional quality of the fermentation substrate itself as is expressly taught by the present disclosure.

Accordingly, the Examiner's grounds for rejection can be reduced to the argument that, based on the similarities in the starting fermentation substrates (although substrates other than those disclosed by Labeille are recited in the present disclosure), the microorganisms, and a fermentation process well known in the art, that the presently claimed invention must be inherently disclosed by the Labeille reference. Respectfully, this is not the proper test under current law on inherent anticipation.

To establish inherency, it is a requirement that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.¹ Mere probabilities or possibilities will not suffice, that is, "[T]he mere fact that a certain thing may result from a given set of circumstances is not sufficient."² Even more, to establish lack of novelty of a claimed invention under 35 U.S.C. §102, a single prior art reference must disclose every element of that invention, arranged as in the claim.³ Any question as to whether the

¹ Manual of Patent Examining Procedure §2163.07(a), citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

² *Id.*

³ *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556, 1560 (Fed. Cir. 1985) ("Anticipation requires the presence in a single prior art reference of all elements of a claimed invention arranged as in the claim," (quoting *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1548 (Fed. Cir. 1983)). *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983) ("A party asserting that a patent claim is anticipated under 35 U.S.C. §102 must demonstrate, among other things, identity of invention ... [O]ne who seeks such a finding [of fact] must show that

cited reference would have resulted in each element of a claimed invention, arranged as in the claim, obviates a rejection on inherency grounds.⁴ Stated differently, there is an element of inevitability to the analysis of inherency, that is, the record must show that the disclosure of the prior art reference inevitably results in the invention as claimed.⁵ The Federal Circuit Court of Appeals requires clear and convincing evidence showing that the claimed invention is necessarily present in the prior art reference to support a finding of inherent anticipation.⁶

In rejecting the claims, the Examiner fails to address that the Labeille reference does not expressly or impliedly teach at least the claim limitations of an increase in protein content and a decrease in fat content of the by-product or residue according to the ranges set forth in the present claims. Nonetheless, the claims are rejected on the contention that Labeille inherently teaches these limitations. The Applicant respectfully traverses the rejection at least because the Office has not met its burden to fully develop reasons supporting its reliance on Labeille.

each element of the claim in issue is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice.”), see also *Net Moneyin, Inc. v. Verisign, Inc.*, Fed. Cir. 2007-1565, Oct. 20, 2008 (Fed. Cir. 2008).

⁴ See *Glaxo, Inc. v. Novopharm Ltd.*, 830 F.Supp. 871, 874 (E.D.N.C. 1993), *aff’d Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1047-48 (Fed. Cir. 1995), rejecting a defense of inherent anticipation because the method disclosed in a prior art patent sometimes resulted in the claimed form of a compound, but sometimes resulted in production of another form.

⁵ See, e.g., *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (reversing the Board of Patent Appeals and Interference’s finding of anticipation by inherency of claimed diaper mechanical fastening system); *Scaltech, Inc. v. Retec/Tetra, LLC*, 178 F.3d 1378, 1384 (Fed. Cir. 1999) (“Inherency may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency.” (citing *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991)).

⁶ *Haberman v. Gerber Products Co.*, 236 F. App’x 592, 598 (Fed. Cir. 2007) (“At most, the testimony ... demonstrates that applying a predetermined level of oral suction may result in the drawing out of liquid via the Brown valve. Such evidence falls short of clear and convincing evidence ...”).

The Office bears a burden to develop reasons supporting a reliance on inherency.⁷ To satisfy this burden, the Office and the Examiner must identify some basis in fact or articulate some reasoning at least tending to show that allegedly inherent subject matter necessarily (i.e., inevitably) flows from cited art. Indeed, the MPEP expressly instructs that:

“In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”⁸

Further, since a basis in fact and technical reasoning is required when inherency is invoked, a failure to provide such evidence or rationale is fatal to the reliance on this doctrine. This is only logical since evidence “must make clear” that the allegedly inherent subject matter is necessarily present in (i.e., necessarily flows from) the disclosure of cited art.⁹ The mere assertion in response to the Applicant’s prior arguments that “[T]he claimed ranges for protein and fat content of the fermented product will be inherent regarding the fermentation duration range of 0-66 hours as disclosed by Labeille” (page 5, paragraph 2a of the latest Action) cannot be reasonably said to be a development of any reason supporting the Office’s reliance on inherency. Consequently, the Action’s reliance on inherency is unsupported and thus improper.

The situation might be different were the Applicant laying claim to a method for improving the nutritional quality of a fibrous by-product or residue of a food manufacturing process or method

⁷ Manual of Patent Examining Procedure §2112(IV).

⁸ *Id.*, citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

⁹ Manual of Patent Examining Procedure §2112.

for producing an animal feed by fermenting the by-product or residue, without more. However, that is not the case. The Applicant's claims include precise language regarding alterations in dry matter, protein, and fat content of the by-product or residue which are not taught or suggested by Labeille. That is, the present claims clearly are directed to improving nutritional qualities of the fermentation product, that is, the substrate, for subsequent use as an animal feed or feed supplement by a precise alteration in dry matter, protein, and fat content of the by-product substrate to render the material suitable as a value-added feed or feed additive.

On the other hand, Labeille teaches a multi-enzyme product, and a method for making it by solid state fermentation of wheat bran for a 1-3 day fermentation period. Labeille focuses on the enzyme resulting from its method, not the nature of the substrate. It is true, as stated by the Examiner, that Labeille mentions feeding its product to monogastric animals (see *paragraph 0038*). However, again, it is the enzyme content of the fermentation substrate that provides the value to the animal, not the substrate ("[I]n this application, it is the xylanase activity which constitutes the most important factor," see *paragraph 0038*).

Thus, clearly even when feeding a substrate to an animal, Labeille is carefully tailoring its fermentation method to optimize the amount and nature of the enzyme fed to the animal, without regard to the nutritional value of the substrate itself. This is more than simply an unrecognized feature of the prior art teaching. Labeille's exclusive focus is the enzyme content, and methods for maximizing production of particular enzymes in accordance with the particular use contemplated for the end product (as recited by Labeille, see *paragraphs 0037-0038*, a product intended for use in ethanol fermentation would require maximum glucoamylase, while a product intended for use as a feed additive for monogastric animals would require maximal xylanase).

Labeille does not expressly, impliedly, or inherently disclose every element of the invention as set forth in the independent claims, arranged as in those claims. The rejection of the independent claims should be withdrawn. The claims depending from the independent claims incorporate all limitations of the claims from which they depend by reference, and are therefore also believed to patentably define over any teaching of Labeille.

With regard to any prospective consideration of obviousness of the amended independent claims over Labeille, the Applicant would reiterate that, given the exclusive enzyme focus of the Labeille disclosure, the skilled artisan is provided no articulated reason to consider the presently recited articular alterations in protein, fat, and dry matter to improve nutritional properties of the by-product or residue. It is an express requirement to support an obviousness rejection, despite any recent revisions to the Manual of Patent Examining Procedure, that the Examiner articulate a reason that the skilled artisan would contemplate making any modification to the reference to arrive at the subject matter of the claims under consideration.¹⁰ Lacking such reason, there is a risk that improper hindsight, potentially based on the teachings of an application under examination, is being used to justify the modification. Lacking any articulated reason to modify the prior art reference, any consideration of rejection of the amended independent claims of the present application over Labeille on obviousness grounds risks improper hindsight analysis. The dependent claims, incorporating by reference the limitations of the independent claims, are similarly believed to be in condition for allowance without consideration of obviousness in accordance with the teachings of *In re Fine*.¹¹

It is believed that the foregoing amendments and arguments overcome the art and rejections

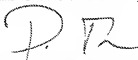
¹⁰ *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 82 USPQ2d 1385 (2007).

¹¹ *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) (“Dependent claims are non-obvious under 35 USC 103 if the claims from which they depend are non-obvious.”).

of record, and properly place the remaining pending claims in condition for allowance. Accordingly, allowance of all remaining claims of the application and issuance of an early Notice of Allowance is respectfully requested. If any issues remain to be addressed, however, the Examiner is respectfully requested to contact the Applicants' attorney at the telephone number of record in order to expedite the prosecution of this patent application. The Commissioner is authorized to deduct the fee for the accompanying Request for Continued Examination and petition for extension of time (three months) from the undersigned's Deposit Account No. **11-0978**.

Respectfully submitted,

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A handwritten signature in dark ink, appearing to read 'P. Torre', written over the printed name of Patrick M. Torre.

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